Supreme Court, U.S.
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In The
Supreme Court of the United States
October Term 1998

ANN WARDER, et al.,

Petitioners,

V.

DONNA E. SHALALA, et al.,

Respondent.

On Petition For A Writ of Certiorari
To the United States Court of
Appeals For the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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I. QUESTIONS PRESENTED FOR REVIEW

1. Is it clear that Congress intended the Medicare "braces" benefit to be restricted by an administrative interpretation which deprives residents of nursing homes from a personal Medicare entitlement to braces which are used in conjunction with other medical or non-medical equipment (such as an arm, leg, back or neck brace attached to a wheeled base or to a wheelchair)?

2. Is HCFA Ruling 96-1's ("HCFAR 96-1) limitation of the Medicare "braces" benefit under 42 U.S.C. § 1395x(s)(9) to only those braces "which are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment" a substantive change in the law which requires prior notice and comment under the Social

Security Act ("SSA") and the Administrative Procedure Act ("APA")?

3. If HCFAR 96-1 is an interpretative ruling published without prior notice and comment, is it entitled to judicial deference?

II. **PARTIES**

A. Petitioners

1. Anne Warder
2. Dorothy Bouchoux
3. Massachusetts Therapeutic Technologies, Inc. ("MATT")
4. Florida Therapeutic Technologies, Inc. ("FTT")
5. The Orthotics Center, Inc. d/b/a OrthoConcepts

OrthoConcepts, MATT and FTT are brother-sister corporations with the same shareholders of each.

B. Respondents

1. Donna E. Shalala
2. Nancy Ann Min deParle

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b. Anne Warder et al. v. Donna E. Shalala, et al., 149 F.3d 73, 57 Soc.Sec.Rep. Serv. 847 (1st Cir. 1998)

c. Anne Warder, et al. v. Donna E. Shalala, et al., No. 97-10424-MEL, 1997 WL 263733, 65 USLW 2799, Medicare & Medicaid Guide (CCH) 1997-1 Transfer Binder, ¶ 45,268 (D. Mass., May 7, 1997)

VI. STATEMENT OF JURISDICTION

Subject matter jurisdiction exists over this Medicare reimbursement dispute pursuant to 42 U.S.C. §1395ff and other applicable law. This Court has appellate jurisdiction, pursuant to 28 U.S.C. 1254(1), to review the decision of the Court of Appeals for the First Circuit. The Court of Appeals entered Judgment for the Secretary on July 27, 1998, the petition for rehearing was denied on October 7, 1998, and the Appellants filed a timely Petition Writ of Certiorari on January 5, 1999. Rules of the Supreme Court 13.

VII. U.S. CONSTITUTIONAL PROVISIONS, TREATIES, STATUTES, RULES, AND REGULATIONS INVOLVED

42 U.S.C. § 1395x. Definitions
(n) Durable medical equipment

The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1395i-3(a)(1) of this title), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual

has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations); except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

42 U.S.C. § 1395x. Definitions

(s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

...

(6) durable medical equipment;

...

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

...

(Full text set forth in Appendix to Petition for Writ of Certiorari at page A-98 to A-110)

P.L. 101-508, § 4152(c)(4)

(3) TREATMENT OF POWER-DRIVEN WHEELCHAIRS AS MISCELLANEOUS ITEMS OF DURABLE MEDICAL EQUIPMENT.

(A) IN GENERAL.-Section 1834(a)(2XA) (42 U.S.C. 1395m(a)(2)(A)) is amended -

(i) in clause (i), by

(i) in clause (i), by inserting "or" at the end;

(ii) in clause (ii), by striking "or" at the end; and

(iii) by striking clause (iii).

(B) CRITERIA FOR TREATMENT OF WHEELCHAIR AS CUSTOMIZED ITEM.-

(i) Section 1834(a)(4) (42 U.S.C. 1395m(a)(4)) is amended by adding at the end the following: "In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for. purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use,

and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician."

(ii) The amendment made by clause (i) shall apply to items furnished on or after January 1, 1992, unless the Secretary develops specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1834(aX4) of the Social Security Act (in which case the amendment made by such clause shall not become effective).

H.R. No. 101-881,101st Cong. 2nd Sess., 1990 USCCAN at 2270

Non-custormized motorized wheelchairs would be recategorized back into the rental cap category of equipment. The option for treating wheelchairs as customized would not be changed.

If the Secretary does not issue regulations defining "customized" wheelchairs by January 1, 1992, a statutory definition would become effective. Under this definition, a customized power driven or manual wheelchair would be defined as a wheelchair which has been: (1) measured, fitted, or adapted in consideration of a patient's body size, disability, length of need or intended use; and (2) has been assembled by the supplier or ordered through a manufacturer who make available customized features, modifications or components that are intended for a specific patient's use in accordance with a physician's order.

In applying this definition, the Committee intends that examples of features that are only available in customized equipment may include, but are not limited to: (1) semi or full reclining backs, (2) special heights for arms, seats or backs, (3) special width or depth of seat, (4) attachments to convert wheelchairs to one-armed drive, (5) postural control devices, (6) custom molded cushions and inserts, or lateral supports.

This definition would become effective on January 1, 1992, unless the Secretary provides for an alternative definition of customized wheelchairs prior to January 1, 1992, in which case the provision would not be effective.

The Secretary would establish a reasonable useful lifetime of rental equipment, including frequently serviced items. The useful lifetime would be 5 years, unless the Secretary finds, based on program experience, that a longer or shorter period is appropriate for an item. After an item's useful lifetime is

reached during a continuous period of medical necessity, the Secretary would provide for a new cycle of rental payments.

Carriers would be permitted to make exceptions, and begin a new cycle of rental payments, for equipment that is lost or irreparably damaged. Such exceptions would only be authorized after special consideration and scrutiny of the circumstances by the carrier.

VIII. STATEMENT OF THE CASE

Section 1861(s)(9) of the Social Security Act (42 U.S.C. §1395x(s)(9)) bluntly states that Medicare beneficiaries are entitled to "leg, arm, back and neck braces." No court has been asked to define what constitutes a "brace" under the Social Security Act.

In Health Care Finance Administration Ruling 96-1 ("HCFAR 96-1") and without explicit congressional direction to do so, the Secretary limited the meaning of "leg, arm, back, and neck braces" to only those braces which "are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment."

HCFAR 96-1 further simply deemed "braces" which are used in conjunction with other medical or non-medical equipment to be "durable medical equipment" ("DME"). By such deeming, HCFAR 96-1 transforms, for example, an arm brace mounted on an exoskeletal base or on a wheelchair from a "brace" to

"DME".

Certain residents of nursing homes suffer such complete musculo-skeletal failure that their braces must be fabricated for use in conjunction with, or as components of, other medical or non-medical equipment. For example, braces for such catastrophically disabled patients often must be anchored to or mounted on medical or non-medical equipment (such as an exoskeletal base or a wheelchair) in order for their braces to properly perform their bracing function.

HCFAR 96-1 removes such braces from the personal Medicare benefits (namely, those under Medicare Part B) of such catastrophically disabled patients in nursing homes. There is no other benefit under Medicare which could reliably provide an alternative source of such braces to catastrophically disabled patients in nursing homes. This deprivation caused by HCFAR 96-1 occurs because DME is not a covered personal benefit under Medicare to residents of

nursing homes.

If not an outright abrogation of the Medicare "braces" benefit for catastrophically disabled residents of nursing homes who need braces, then, Petitioners contend, HCFAR 96-1 is a substantive change in the law and required prior notice and comment.

The District Court ruled, inter alia, that HCFAR 96-1 effected a substantive change in Medicare law, which required prior notice and comment under the Administrative Procedure Act and the Social Security Act. The District Court enjoined the Secretary from enforcing HCFAR 96-1. The Court of Appeals reversed the District Court. Petitioners here appeal the decision of the First Circuit Court of Appeals.

IX. ARGUMENT

1. Is it clear that Congress intended the Medicare "braces" benefit to be restricted by an administrative interpretation which deprives residents of nursing homes from a personal Medicare entitlement to braces which are used in conjunction with other medical or non-medical equipment (such as an arm, leg, back or neck brace attached to a wheeled base or to a wheelchair)?

Petitioners submit that it is clear that Congress did not intend for braces to be denied to catastrophically disabled Medicare beneficiaries who are residents of nursing homes. Yet, such denial is precisely the effect of HCFAR 96-1. Because of its impact on the weakest members of society, the validity of HCFAR 96-1 raises an important question of federal law that has not been, but should be, settled by the

Supreme Court. Rules of Supreme Court ("RSC") 10.

The above question and Petitioners' submitted answer above provide a departure point for analysis of the validity of HCFAR 96-1 under Chevron U.S.A., Inc. v. NRDC, 467 U.S. 8737 (1984).

As Justice Scalia has noted in discussing Chevron, where

> Congress intended a particular result, but was not clear about it . . . what we have is genuinely a question of law, properly to be resolved by the courts.

Scalia, Judicial Deference to Administrative Interpretation of Law, 1989 DUKE L.J. 511, 516.

As Justice Scalia noted further in the same article,

> Here [referring to the question

> of how to determine whether the Congressional intent is clear or ambiguous] . . . is the chink in Chevron's armor -- the ambiguity that prevents it from being an absolutely clear guide to future judicial decisions . . . How clear is clear?

Id. at 520.

Petitioners' case provides an opportunity for the Court to "fill the chink in Chevron's armor" by providing guidance to answer Justice Scalia's question of "How clear is clear?" in assessing whether Congress has spoken clearly enough, so as to preclude an administrative rule (such as HCFAR 96-1) which frustrates Congress' intent to provide braces to patients in nursing homes. The question of "How clear is clear?" is an important question of federal law which has not been, but should be, decided by the Supreme Court.

When Congress intends not to provide a benefit to patients in a nursing home,

it does so plainly. It did so in denying DME benefits to patients in nursing homes by defining coverage for DME to be limited to use in a patient's "home" (which is defined as other than a hospital under 42 U.S.C. §1395x(e)(1) or a skilled nursing facility under 42 U.S.C. 1395i-3(a)(1)). 42 U.S.C. § 1395x(n). Congress has also shown that it is capable of expressing its intent that the Secretary further define DME, as it did when it required the Secretary to promulgate regulations defining a customized wheelchair. P.L. 101-508, § 4152(c)(4); H.R. No. 101-881, 101st Cong. 2nd Sess., 1990 USCCAN at 2770. Congress has shown no intent to limit the brace benefit by constrictive interpretations issued without notice and comment.

2. Is HCFA Ruling 96-1's ("HCFAR 96-1") limitation of the Medicare "brace" benefit under 42 U.S.C. § 1395x(s)(9) to only those braces "which are used independently rather than in conjunction with, or as components of, other medical or

non-medical equipment" a substantive change in the law which requires prior notice and comment under the Social Security Act ("SSA") and the Administrative Procedure Act ("APA")?

HCFAR 96-1 is a substantive (a/k/a "legislative") rule, rather than an interpretive rule because it

> . . . imposes obligations, the basic tenor or which is not already outlined in the law itself . . .

La Casa del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992). Among other burdens, an obligation imposed by HCFAR 96-1 which is not already outlined in the law is that HCFAR 96-1 deprives catastrophically disabled Medicare beneficiaries who reside in nursing homes of a right to braces, simply because the fabrication of their braces necessitates the use of such braces in conjunction with other medical

or non-medical equipment.

Nowhere on the face of the Medicare brace benefit, set forth in 42 U.S.C.§1395x(s)(9), did Congress hint at such a restriction. Because Congress did not hint at such a restriction, HCFAR 96-1 cannot be an interpretation of existing law. Therefore HCFAR 96-1 should have been published for notice and comment pursuant to the SSA and the APA. 42 U.S.C. §1395hh and 5 U.S.C. §553(b).

Nevertheless, the above question presents an important question of federal law that has not been, but should be, decided by the Supreme Court. As the First Circuit noted in Petitioner's case

> The line between a legislative or substantive rule and an interpretative one is, as many courts have noted, far from clean.

Ann Warder, et al. v. Donna E. Shalala, et al., 149 F.3d 73, 79 (1st Cir. 1998), citing e.g., Convaleciente, 965 F.2d at 1177. See also, What Constitutes

"Interpretative Rule" of Agency So As to Exempt Such Action from Notice Requirements of Administrative Procedure Act (5 U.S.C.A. §553(B)(3)(A), 126 A.L.R. 347 (1995); Herz, Deference Running Riot: Separating Interpretation and Law-marking Under Chevron, 6 ADMIN. L.J. (1992); Crouse, Benten v. Kesser: The Time for Uniformity in the Application of Section 553 of the Administrative Procedure Act Has Come, 7 ADMIN. L.J. (1993).

3. If HCFAR 96-1 is an interpretative ruling published without prior notice and comment, is it entitled to judicial deference?

This is an important question of federal law that has not been, but should be, settled by the Supreme Court. Chevron involved a rule issued with prior notice and comment. Such prior notice and comment was calculated to involve appropriate political participation. See Scalia, Id. at 517. HCFAR 96-1's promulgation without notice and comment raises an important issue of whether

judicial deference should be given to an agency interpretation made without prior public, outside expert, or political involvement and accountability as contemplated by the notice and comment provisions of APA and the SSA.

Moreover, the Supreme Court should decide this question because

> a United States court of appeals has entered a decision [on this question] in conflict with the decision of another United States court of appeals on the same important matter.

Rules of Supreme Court 10(a).

As the First Circuit noted below in Petitioner's case

> A threshold question is what deference is owned to an interpretative rule such as HCFAR 96-1. *The Supreme Court has not expressed a view on whether or to what extent the* <u>*Chevron*</u> *framework* .

> . . *applies to interpretive rather than legislative rules, and other circuits are split on the issue."* (Emphasis supplied), citing at footnote 8: Compare Trans Union Corp. v. FTC, 81 F.3d 228, 230 (D.C. Cir 1996) ("[W]e have extended Chevron deference to agency interpretive rules . . . indeed, the rule at issue in Chevron itself appears to have been interpretive."), and, Elizabeth Blackwell Health Ctr. For Women v. Knoll, 61 F.3d 170 (3d Cir. 1995) (equal deference), and, Garcia v. Secretary of Health & Human Servs., 46 F.3d 552, 556 (6th Cir. 1995)(same) with Atchison, Topeka & Santa Fe Ry. Co. v. Pena, 44 F.3d 437, 442 (7th Cir. 1994) (en banc) (concluding that interpretive rules are "underserving of deference under Chevron").

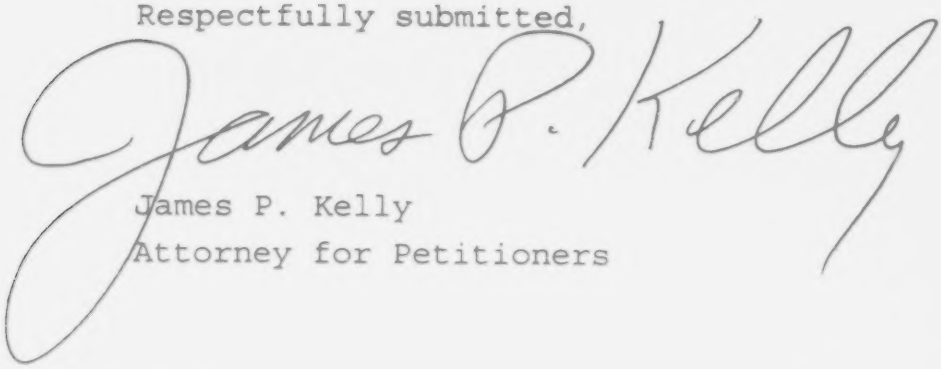
The question of whether deference should be extended to HCFAR 96-1 was not answered by Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 115 S. Ct. 1232 (1995). Guernsey involved a narrow gap

"unaddressed by the otherwise comprehensive regulations on [a] particular subject." Id. at 97. In contrast to Guernsey's gap, HCFAR 96-1 broadly addresses a whole subject matter of an enumerated Medicare benefit, namely "braces" as set forth in 42 U.S.C. §1395x(s)(9), about which there are few regulations. Moreover, HCFAR 96-1 raises broad policy questions of important federal law of why place of residence (namely, in a nursing home or not) should deprive catastrophically disabled Medicare beneficiaries of the particular types of braces they need (namely, braces used in conjunction with other medical or non-medical equipment).

For the above reasons, and as may be required by justice, Petitioners respectfully request that the Supreme Court issue a Writ of Certiorari regarding this petition and the questions presented herein.

This 5th day of January, 1999.

Respectfully submitted,



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